

**In The United States Patent and Trademark Office**

Appn. Number: 10/017568

Appn. Filed: 12/14/2001

Applicant: Michael B. Zemel

Title: Materials and Methods for The Treatment and  
Prevention Of Obesity

Examiner/ GAU: Abigail Fisher/ 1616

**Declaration Under 37 C.F.R. § 1.131**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Dr. Michael B. Zemel Declares:

1. I am an inventor of the invention disclosed and claimed in U.S. Application Serial Number 10/017568. Furthermore, I am a researcher in the area of obesity, adipocytes, and vitamin D metabolites. I have published an article titled *Calcitriol and Energy Metabolism* (Nutrition Reviews, Vol 66 (Suppl. 2): s139-s146, 2008) that

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summarized my research on the effect of vitamin D metabolites on adipocytes.

2. I did not expect either  $1\alpha$ , 25-dihydroxyvitamin  $D_3$  or  $1\beta$ , 25-dihydroxyvitamin  $D_3$  to affect lipolysis or lipogenesis in adipocytes.

3. I believe that, at the time of my research, a person skilled in the art would not have expected either  $1\alpha$ , 25-dihydroxyvitamin  $D_3$  or  $1\beta$ , 25-dihydroxyvitamin  $D_3$  to affect lipolysis or lipogenesis in adipocytes. I further believe that, at the time of my research, a person skilled in the art would not have expected any vitamin D metabolite to affect energy metabolism or affect the production or loss of fat in a person.

4. I believe that, at the time of my research, a person skilled in the art would have been unable to determine what effect, if any, a vitamin D metabolite would have on the adipocyte of a person based upon the invention presented in the patent by Norman (United States Patent Number 6103709). I further believe that, at the time of my research, a person skilled in the art would have been unable to determine what effect, if any,  $1\alpha$ , 25-dihydroxyvitamin  $D_3$  or  $1\beta$ , 25-dihydroxyvitamin  $D_3$  would have on the adipocyte of a

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person based upon the invention presented in the patent by Norman.

5. I am an author of an article by Xue, et al (*The Agouti Gene Products Inhibits Lipolysis in Human Adipocytes via a  $Ca^{2+}$ -Dependent Mechanism*, FASEB J, vol. 12, p. 1391-1396, Oct 1998). I believe that, at the time of my research, a person skilled in the art would have been unable to determine what effect, if any, a vitamin D metabolite would have on the adipocyte of a person based upon the research presented in the article by Xue. I further believe that, at the time of my research, a person skilled in the art would have been unable to determine what effect, if any,  $1\alpha$ , 25-dihydroxyvitamin  $D_3$  or  $1\beta$ , 25-dihydroxyvitamin  $D_3$  would have on the adipocyte of a person based upon the research presented in the article by Xue. Furthermore, I state that the Xue article did not address the question of what effect vitamin D metabolites,  $1\alpha$ , 25-dihydroxyvitamin  $D_3$ , or  $1\beta$ , 25-dihydroxyvitamin  $D_3$  had on the adipocyte of a person.

I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

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statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and such willful false statements my jeopardize the validity of the application or any patent issued thereon.

Further, Declarants sayeth not.

By: 

Michael B. Zemel, Ph.D.

Date:  26, 2009